JUN 3 - 2005

K050795

510(k) SUMMARY

IMBIBE Bone Marrow Aspiration Needle

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Phone: (610) 407-5211
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Contact Person: David McIlhenny
Sr. Vice President, Operations

Date Prepared: March 10, 2005

Name of Device

Imbibe™ Bone Marrow Aspiration Needle

Common or Usual Name

Aspiration Needle, BMA Needle

Classification Name

Needle, Aspiration and Injection, Disposable (Product Code GAA)

Predicate Devices

510(K) Number	Predicate Description	Manufactured By
K940025	Bone Marrow Harvest Needle	Manan Medical
K001132	Bone Biopsy Needle	Promex
K041991	Aspirex – Bone Marrow Aspiration Kit	Isotis Orthobiologics

Intended Use / Indications for Use

The Imbibe Bone Marrow Aspiration Needle is for use in aspirating Bone Marrow or Autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.

Technological Characteristics

The Imbibe Bone Marrow Aspiration Needle consists of an 8ga or 11ga needle, trocar tip stylet of corresponding size, and bullet tip stylet of corresponding size. The needle will be manufactured in two lengths measuring 10cm or 15cm from tip to molded handle. A female luer is provided on the molded needle handle to allow aspiration of bone marrow or blood by use of a standard surgical syringe. One version of the 8ga needle provides fenestrated holes on the distal end of the needle. The fenestrated holes in the distal end of the needle are designed to provide more area for bone marrow or blood to enter the needle during aspiration. The bullet tip stylet must be inserted into the needle, after initial needle placement, if repositioning of the needle is required. If required, the needle can be lightly tapped with a surgical hammer for placement.

Performance Data

Performance testing provided in the submission indicates that the Imbibe Bone Marrow Aspiration Needle met all of the established specifications. Mechanical and performance testing verified that the Imbibe Bone Marrow Aspiration Needle is substantially equivalent to the predicate devices for bone marrow aspiration and does not raise any new issues of safety and effectiveness.

Summary Basis for the Finding of Substantial Equivalence

The Imbibe Bone Marrow Aspiration Needle is substantially equivalent to the predicate devices. The Imbibe Bone Marrow Aspiration Needle has the same intended uses and similar indications, technological characteristics and principles of operation. The minor technological differences between the Imbibe Bone Marrow Aspiration Needle and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates the Imbibe Bone Marrow Aspiration Needle is as safe and effective as the predicate devices. Thus, the Imbibe Bone Marrow Aspiration Needle is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Orthovita Incorporated
C/o Ms. Janice M. Hogan
Regulatory Counsel
Hogan & Hartson, L.L.P
1835 Market Street, 28th Floor
Philadelphia, Pennsylvania 19103

Re: K050795
Trade/Device Name: Imbibe Bone Marrow Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: March 24, 2005
Received: March 29, 2005

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K050795

Device Name: Imbibe Bone Marrow Aspiration Needle

Indications for Use:

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Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050795